MRO's request may either be a general request covering all such results you send to the MRO or a specific case-by-case request.

(f) You must provide quantitative values for confirmed opiate results for morphine or codeine at 15,000 ng/mL or above, even if the MRO has not requested quantitative values for the test result.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.99 How long does the laboratory retain specimens after testing?

(a) As a laboratory testing the primary specimen, you must retain a specimen that was reported with positive, adulterated, substituted, or invalid results for a minimum of one year.

(b) You must keep such a specimen in secure, long-term, frozen storage in accordance with HHS requirements.

(c) Within the one-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain a specimen for an additional period of time (*e.g.*, for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the specimen at the end of the year.

(d) If you have not sent the split specimen to another laboratory for testing, you must retain the split specimen for an employee's test for the same period of time that you retain the primary specimen and under the same storage conditions.

(e) As the laboratory testing the split specimen, you must meet the requirements of paragraphs (a) through (d) of this section with respect to the split specimen.

§ 40.101 What relationship may a laboratory have with an MRO?

(a) As a laboratory, you may not enter into any relationship with an MRO that creates a conflict of interest or the appearance of a conflict of interest with the MRO's responsibilities for the employer. You may not derive any financial benefit by having an employer use a specific MRO.

(b) The following are examples of relationships between laboratories and MROs that the Department regards as creating conflicts of interest, or the appearance of such conflicts. This following list of examples is not intended to be exclusive or exhaustive:

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the employer a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

§ 40.103 What are the requirements for submitting blind specimens to a laboratory?

(a) As an employer or C/TPA with an aggregate of 2000 or more DOT-covered employees, you must send blind specimens to laboratories you use. If you have an aggregate of fewer than 2000 DOT-covered employees, you are not required to provide blind specimens.

(b) To each laboratory to which you send at least 100 specimens in a year, you must transmit a number of blind specimens equivalent to one percent of the specimens you send to that laboratory, up to a maximum of 50 blind specimens in each quarter (*i.e.*, January–March, April–June, July–September, October–December). As a C/TPA, you must apply this percentage to the total number of DOT-covered employees' specimens you send to the laboratory. Your blind specimen submissions must be evenly spread throughout the year. The following examples illustrate how this requirement works:

Example 1 to Paragraph (b). You send 2500 specimens to Lab X in Year 1. In this case,

you would send 25 blind specimens to Lab X in Year 1. To meet the even distribution requirement, you would send 6 in each of three quarters and 7 in the other.

Example 2 to Paragraph (b). You send 2000 specimens to Lab X and 1000 specimens to Lab Y in Year 1. In this case, you would send 20 blind specimens to Lab X and 10 to Lab Y in Year 1. The even distribution requirement would apply in a similar way to that described in Example 1.

Example 3 to Paragraph (b). Same as Example 2, except that you also send 20 specimens to Lab Z. In this case, you would send blind specimens to Labs X and Y as in Example 2. You would not have to send any blind specimens to Lab Z, because you sent fewer than 100 specimens to Lab Z.

Example 4 to Paragraph (b). You are a C/TPA sending 2000 specimens to Lab X in Year 1. These 2000 specimens represent 200 small employers who have an average of 10 covered employees each. In this case you—not the individual employers—send 20 blind specimens to Lab X in Year 1, again ensuring even distribution. The individual employers you represent are not required to provide any blind specimens on their own.

Example 5 to Paragraph (b). You are a large C/TPA that sends 40,000 specimens to Lab Y in Year 1. One percent of that figure is 400. However, the 50 blind specimen per quarter ''cap'' means that you need send only 50 blind specimens per quarter, rather than the 100 per quarter you would have to send to meet the one percent rate. Your annual total would be 200, rather than 400, blind specimens.

(c) Approximately 75 percent of the specimens you submit must be blank (*i.e.*, containing no drugs, nor adulterated or substituted). Approximately 15 percent must be positive for one or more of the five drugs involved in DOT tests, and approximately 10 percent must either be adulterated with a substance cited in HHS guidance or substituted (*i.e.*, having specific gravity and creatinine meeting the criteria of § 40.93(b)).

(1) The blind specimens that you submit that contain drugs, that are adulterated with a substance cited in HHS guidance, or that are substituted must be validated as to their contents by the supplier using initial and confirmatory tests.

(2) The supplier must provide information regarding the shelf life of the blind specimens.

(3) If the blind specimen is drug positive, the concentration of drug it contains must be between 1.5 and 2 times the initial drug test cutoff concentration.

(4) If the blind specimen is adulterated with nitrite, the concentration of nitrite it contains must be between 1.5 and 2 times the initial validity test cutoff concentration.

(5) If the blind specimen is adulterated by altering pH, the pH must be less than or equal to 2, or greater than or equal to 12.

(6) If the blind specimen is substituted, the creatinine must be less than or equal to 2, and the specific gravity must be 1.000.

(d) You must ensure that each blind specimen is indistinguishable to the laboratory from a normal specimen.

(1) You must submit blind specimens to the laboratory using the same channels (*e.g.*, via a regular collection site) through which employees' specimens are sent to the laboratory.

(2) You must ensure that the collector uses a CCF, places fictional initials on the specimen bottle label/seal, indicates for the MRO on Copy 2 that the specimen is a blind specimen, and discards Copies 4 and 5 (employer and employee copies).

(3) You must ensure that all blind specimens include split specimens.

§ 40.105 What happens if the laboratory reports a result different from that expected for a blind specimen?

(a) If you are an employer, MRO, or C/TPA who submits a blind specimen, and if the result reported to the MRO is different from the result expected, you must investigate the discrepancy.

(b) If the unexpected result is a false negative, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy.

(c) If the unexpected result is a false positive, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy. You must also notify ODAPC of the discrepancy by telephone (202–366–3784) or e-mail (addresses are listed on the ODAPC web site, http://